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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,296	05/24/2005	Andreja Vukmirovic	BPPG-32982A/LEK	9213
7590 11/09/2009				
Mark S. Graham, Esq. LUEDEKA, NEELY & GRAHAM, P.C. P.O. Box 1871 Knoxville, TN 37901				
EXAMINER				
HOLLOMAN, NANNETTE				
ART UNIT		PAPER NUMBER		
1612				
MAIL DATE		DELIVERY MODE		
11/09/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Advisory Action**  
**Before the Filing of an Appeal Brief**

**Application No.**

10/521,296

**Applicant(s)**

VUKMIROVIC ET AL.

**Examiner**

NANNETTE HOLLOMAN

**Art Unit**

1612

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 23 October 2009 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 4 months from the mailing date of the final rejection.  
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.  
Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**NOTICE OF APPEAL**

2. ☒ The Notice of Appeal was filed on 23 October 2009. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

**AMENDMENTS**

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☐ They raise the issue of new matter (see NOTE below);  
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
The status of the claim(s) is (or will be) as follows:  
Claim(s) allowed: \_\_\_\_\_.  
Claim(s) objected to: \_\_\_\_\_.  
Claim(s) rejected: 1-13, 19 and 20.  
Claim(s) withdrawn from consideration: 14, 15 and 21.

**AFFIDAVIT OR OTHER EVIDENCE**

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

**REQUEST FOR RECONSIDERATION/OTHER**

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See Continuation Sheet.  
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_.  
13. ☐ Other: \_\_\_\_\_.

/Frederick Krass/  
Supervisory Patent Examiner, Art Unit 1612

/N. H./  
Examiner, Art Unit 1612

Continuation of 11. does NOT place the application in condition for allowance because: Claims 1-13 were rejected under 35 U.S.C. 102(b) as being anticipated by Woog et al. (US Patent No. 4,992,419). This rejection is maintained.

**Applicant's Arguments:** Applicant argues the specification teaches "consisting essentially of" is adequately elucidated, having been explained as excluding additional EPO stabilizers other than polyvinylpyrrolidone (PVP), and , optionally, a poloxamer stabilizer. Applicant further argues example 5 of Woog et al., which does not list urea, is obviously an error. Applicant's arguments have been fully considered but they are not persuasive.

**Examiner's Response:** As previously asserted the term "consisting essentially of" is inadequately described by the instant specification, since it fails to contemplate the exclusion of any particular ingredients as implied therein; nor does it provide any criteria for determining if a given ingredient "materially affects the basic or novel characteristics of the invention". Applicant points to the specification at page 5, last paragraph, that "In the pharmaceutical composition of the present invention, besides the pH buffering system and optionally besides an isotonicifying agent and/or a further pharmaceutically acceptable excipients PVP alone may be used as the effective EPO stabilizer and no further stabilizers are necessary for stabilizing EPO. PVP can therefore replace the combinations of different stabilizers which are known to be used to maintain the EPO stability in pharmaceutical compositions of EPO described in the prior art," would teach PVP as the primary, and in many cases the only, EPO stabilizer needed in the claimed composition. However, applicant has failed to show that the introduction of additional components would materially change the characteristics of Applicant's invention. Furthermore, as previously asserted, at page 4, lines 10-25 of the instant specification, Applicant discloses a preferred embodiment of a composition "comprising", which is open language, components a.-c. and optionally d. and e.

In regard to Applicant's assertion that Woog's example 5 is obviously an error, a patent is considered to be valid and therefore EXAMPLE 5 would appear to not contain urea as a stabilizer. Furthermore, examples in TABLE 2 do not contain urea, i.e. Expt. No. 895 and 897.

Claims 16, 19 and 20 were rejected under 35 U.S.C. 103(a) as being unpatentable over Woog et al. (US Patent No. 4,994,419) as applied to claims 1-13 above, and further in view of Cymbalista (US Patent No. 4,647,454). This rejection is maintained. Claim 16 is cancelled.

**Applicant's Arguments:** Applicant argues Woog does not teach PVP and a poloxamer as the sole or even the essential stabilizer for EPO and Cymbalista does not cure the deficiencies of Woog. Applicant also argues claims 19 and 20 exclude the use of EPO stabilizers other than PVP and poloxamer. Applicant further argues, Cymbalista uses PVP to stabilize interferon beta, not EPO and one of ordinary skill in the art would recognize that a stabilizer which is effective for one protein may be inappropriate for stabilizing a different protein. Applicant's arguments have been fully considered but they are not persuasive

**Examiner's Response:** In regard to Woog, see Examiner's response supra. Furthermore, as disclosed in the Office Action filed October 17, 2008, Woog et al. disclose a composition comprising EPO, PVP (KOLLIDON 12 PF) and buffers in TABLE 1, formulations s1 and b, therefore encompassing the claimed limitations. In regard to claims 19 and 20, the use of "consists" in the body of the claims does not limit the open-ended "comprises" language recited in the preamble of the claim. In regard to Cymbalista, as previously asserted Cymbalista was used to disclose that PVP has been shown to be a highly effective stabilizer of a protein (column 3, line 67 and Tables 1-6). It is prima facie obviousness to select a known material based on its suitability for its intended use. Also, established precedent holds that it is generally obvious to add known ingredients to known compositions with the expectation of obtaining their known function. MPEP 2144.07. Therefore, it would have been obvious to have used PVP as the sole stabilizer of Woog et al. motivated by the desire to use a material known for its stabilizing properties. In addition, in KSR v. Teleflex, 82 USPQ2d 1385, 1397 (U.S. 2007), the Supreme Court has held that when there is market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person has good reason to pursue known options within his or her technical grasp. Under these conditions, "obviousness to try" such options is permissible. In this instance, a market pressure exists in the medical/pharmaceutical industries to achieve long-term EPO stabilization. Accordingly, it would have been obvious to have tried the stabilizer PVP in the formulation of Woog et al. motivated by the desire to achieve maximum stability as disclosed by Cymbalista.